ENGINEERING, FACILITIES, AND EQUIPMENT

Biomedical Equipment Maintenance

P-Number List On The Web

In an attempt to take advantage of the technology available to us, AFMLO has added the P-Number list to the homepage under the Clinical Engineering section. Searches can be run on this database by either P-number or manufacturers name. This database will be updated every time a new P-number is requested and will eventually eliminate the need to publish a paper copy every year. Comments are welcome. (AFMLO/FOM-E, TSgt Stephen Walker, DSN 343-4039)

Frequency Converter Power Harness Correction

A frequency converter (NSN 6130-01-433-3718) procured through Avionics Instruments may have an incorrect mating connector on the power harness. Although Avionics Instruments has notified each activity which may have received frequency converters recently, we want to ensure all "ship-to" addresses are notified of the potential problem. Please follow instructions on page 6 of **Attachment 1** provided by Avionics Instruments. If you have any problems or questions, contact AFMLO. (AFMLO/FOM, Capt Rik Owen, DSN 343-4082)

New Blanket Purchase Agreement (BPA) for Physio-Control Defibrillators

Department of Veterans Affairs (DVA) Special Services at AFMLO awarded a blanket purchase agreement (BPA) against the Federal Supply Schedule (FSS) for Lifepak 10 defibrillators, repair kits, and accessories (see **Attachment 1**, pages 7 through 40). FSS contract BPA's eliminate contracting and open market costs such as search for sources, the development of technical documents and solicitations, and the evaluation of bids and offers.

This BPA was negotiated in an attempt to arm you with additional procurement tools that would provide the lowest price available. Any Government contracting official may place calls against this BPA by calling Physio-Control and referencing BPA # V797(F1)P-BPA-97-00002. Your local contracting office can place calls against this BPA or you can forward your requirements to Mary Boyd, the VA contracting officer at AFMLO. There is no surcharge for using this BPA and it is set up with tiered pricing by quantity ordered as follows:

Discount
FSS price
20% off FSS price
24% off FSS price
28% off FSS price
35% off FSS price

This BPA *guarantees the lowest price* available to the government for these items. Several configurations are available, including NSNs 6515-01-439-6694 and 6515-01-429-1381 as well as aeromedical evacuation (AE) approved units. This BPA is available for use by all government agencies. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

CE-1 AFMLL 25/26-96

Procedures for Obtaining and Completing Food and Drug Administration (FDA) Report of Assembly (FDA Form 2579)

The Code of Federal Regulations (CFR), Title 21, Part 1020 requires x-ray assemblers to report the completion of an x-ray installation to the FDA. The FDA has developed Form FDA 2579, Report of Assembly, for this purpose. Assemblers are responsible for ensuring the form is obtained, completed, and properly distributed. Air Force BMETs who assemble x-ray systems are considered assemblers and must follow these guidelines.

Forms FDA 2579 (current edition 5/90) can be obtained from the Center for Devices and Radiological Health (CDRH), Office of Compliance and Surveillance, 1390 Piccard Drive, Rockville MD 20850, (301) 427-1254. Following installation of one or more certified components of an x-ray system, assemblers must complete an FDA 2579 in accordance with the procedures outlined in AFI 168-407, Medical Equipment Maintenance, paragraphs 4.9.2 and 4.9.3. Distribution procedures vary according to who performs the assembly, and the site location of the installation.

If the installation is performed within the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, or Guam, the following is required: Air Force assemblers must provide the original (white copy) and the state agency copy (yellow copy) to AFMLO/FOM within 15 days of installation. If the contractor is the assembler, he must provide the original to the CDRH within 15 days of the installation. The medical maintenance activity will then provide the yellow copy to AFMLO/FOM.

For all installations, the purchaser copy (pink copy) is placed in the equipment data file (EDF) within the medical maintenance activity. The CDRH does not require a copy if the installation occurs in a location other than those listed above. At these other locations, the BMET should place the original copy and the pink copy in the EDF, and forward the yellow copy to AFMLO/FOM within 15 days of the installation.

The FDA 2579 must remain in the medical maintenance activity EDF until all components listed on it are relocated, transferred, or permanently removed from service. (AFMLO/FOM-E, Mr. David Baker, Jr., DSN 343-7487)

Facility Management

DMLSS-FM Application Survey

As you know, the deployment of the Facility Management application, Release 1 of the Defense Medical Logistics Standard Support (DMLSS) Automated Information System is underway. Some of our facilities have had the opportunity to attend training at Sheppard AFB TX. Additional sessions are scheduled throughout 1997. The facilities are being scheduled for future sessions depending on where the facility falls on the deployment schedule. To ensure the deployment of Release 1 of the FM application is successful, and help prepare for the deployment of computer-aided design (CAD) capability with Release 2, we request you complete the DMLSS-FM survey at Attachment 1, pages 3 through 5. The survey addresses two main areas: the database, and the computer aided design. Not all facilities have received the database build program but we still need you to complete the entire survey. Return the survey to AFMLO by faxing to (301) 619-2958 or 2557, DSN 343-2958 or 2557. Or mail the survey to the following address:

> AFMLO/FOM ATTN: Capt Dick Hart 1423 Sultan Drive, Suite 200 Fort Detrick, MD 21702-5006

Please return your completed survey by 30 January 1997. (AFMLO/FOM-F, Capt Dick Hart, DSN 343-4081)

Quality Assurance

CE-2 AFMLL 25/26-96

Food and Drug Administration (FDA) Recalls/Alert Notices

Attachment 2, paragraph 1, provides information on FDA medical equipment recalls and alerts. Personnel from clinical engineering, biomedical equipment maintenance, quality assurance, and safety should follow the guidance provided to ensure the effective maintenance and management of medical equipment. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Medical Equipment Management

DPSC Medical Equipment Office Catalog Available

The DPSC Medical Equipment Office Information Booklet is contained at **Attachment 1**, pages 41 through 153. The booklet contains information on radiographic film and accessories, biomedical systems/diagnostic imaging, customer order lists (COLs) for existing equipment contracts, equipment available through the Medical/Surgical (Med/Surg) Prime Vendor (PV) Program, and military unique items.

It should be noted equipment available through the Med/Surg PV program is *not* a mandatory source of supply. Normal Med/Surg PV surcharges will apply and activities should consider this when determining which contracting source will provide the best value. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Shared Procurement Equipment Items Currently Available

Attachment 1, pages 1 and 2, contains a list of all current Shared Procurement contracts and

nonmandatory optional contracts available through the Defense Personnel Support Center (DPSC). If you plan to order any of these items for your facility, use the specific ordering instructions and overall program guidance contained in AFMLL 16-96, pages CE-4 and CE-5. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

"Piggyback" Contracts Currently Available

AFMLL 16-96, Attachment 1, pages 4 and 5, contains a list of all current "piggyback" contracts currently available through DPSC. These contracts will allow facilities to "piggyback" requirements onto existing orders placed for specific quantities. Many of these contracts are designed to buy large quantities at reduced prices, and are written with the option of buying additional quantities at the same price. The list includes available quantities and "Order By" dates. To order, send your MILSTRIP requisitions to DPSC and reference the contract number (from the listing) in the notes section. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

JEFFREY W. COOPER, Colonel, USAF, MSC Chief, Air Force Medical Logistics Office

CE-3 AFMLL 25/26-96